

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

| | |
|--|---|
| IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION | Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE |
| THIS DOCUMENT RELATES TO WAVE 4 CASES ON ATTACHED EXHIBIT A | |

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF
DAUBERT MOTION TO PRECLUDE OR LIMIT OPINIONS OF
DEFENSE EXPERT SARAH ABBIE COLLINS**

TABLE OF CONTENTS

| | |
|--|----|
| INTRODUCTION..... | 1 |
| LEGAL STANDARD..... | 2 |
| ARGUMENT..... | 2 |
| I. DR. COLLINS’ GENERAL OPINIONS ON WARNINGS SHOULD BE PRECLUDED OR LIMITED..... | 2 |
| II. DR. COLLINS’ GENERAL OPINIONS ON THE DESIGN AND SCIENTIFIC PROPERTIES OF THE TVT AND TVT-EXACT SHOULD BE PRECLUDED OR LIMITED..... | 6 |
| CONCLUSION..... | 12 |

Plaintiffs respectfully request that this Court exclude certain expert testimony proffered by Defendants Ethicon, Inc. and Johnson & Johnson's expert Sarah Abbie Collins, M.D. ("Dr. Collins"). In support of their motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Sarah Collins is an Obstetrician/Gynecologist with a subspecialty in Pelvic Floor Medicine and Reconstructive Surgery, and Plaintiffs do not challenge her qualifications as such.¹ Dr. Collins' general reports set forth opinions on all liability issues with regard to the TVT and TVT-Exact, including failure to warn and design defect, to include opinions on the material properties of polypropylene mesh. However, Dr. Collins has no experience with the design of a mesh device, study or teaching of warnings, and has admitted to a lack of foundational knowledge. Furthermore, Dr. Collins has a huge gap in her reliance base, as she did not rely on any internal Ethicon documents, and has not reviewed or relied on deposition testimony of any Ethicon witnesses. Dr. Collins' admitted to reviewing only two or three internal Ethicon documents after she had already finalized her report.² She essentially knows nothing about the majority of the evidence and testimony that will be presented to the jury at trial.

Dr. Collins' experience in the field of Obstetrics and Gynecology does not render all of her opinions admissible. The admission of Dr. Collins' unfounded opinions is both contrary to law and presents a serious risk of confusing the issues and misleading the jury.³ As this Court previously noted, "[j]ust because an expert may be 'qualified . . . by knowledge, skill, experience,

¹ Wave 4 Expert Report of Sarah Collins, M.D. TVT and TVT-Exact at p. 2 (attached as Ex. B); *see also* Curriculum Vitae of Dr. Collins (attached as Ex. C).

² Collins 3/6/2017 Dep. at 136:1-137:12, 138:11-14, 195:9-15, 317:11-22 (attached as Ex. D).

³ *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.'") (citing *Daubert*, 509 U.S. at 596).

training or education’ does not necessarily mean that the opinion that the expert offers is ‘the product of reliable principles and methods’ or that the expert ‘has reliably applied the principles and methods to the facts of this case.’”⁴ Accordingly, Dr. Collins should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104.⁵ The trial judge acts as a gatekeeper for scientific, technical, and other specialized knowledge.⁶

ARGUMENT

I. Dr. Collins’ General Opinions on Warnings Should Be Precluded or Limited

Dr. Collins’ opinions regarding the adequacy of defendants’ warnings are based, by her own admission, on nothing more than her clinical practice and experience.⁷ Dr. Collins’ opinions on the warnings are bare conclusions, based solely on what is adequate for her in her own practice, without reference or consideration to any standards or criteria. She has no knowledge of governmental (FDA) regulations or defendants’ internal standards, which are reflective of industry norms and predicated upon FDA regulations. She has no knowledge of any other criteria regarding the contents of adequate warnings.⁸ She concerned herself only with

⁴ *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, *42-43 (S.D.W.V. 2013).

⁵ *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony).

⁶ *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 141 (1999).

⁷ Collins 3/6/2017 Dep. at 121:2-13, 122:2-21, 249:20-250:13, 324:11-22.

⁸ *Id.* at 321:9-21.

what she personally believes surgeons like her ought to know, thus there is no objective basis for any of her opinions.⁹ Her opinions are the very *ipse dixit* that federal courts, including the nation's highest, have repeatedly found inadmissible.

Dr. Collins offers her opinion on the adequacy of Ethicon's warnings but admitted that she only definitively reviewed the 2015 TVT and TVT Exact Instructions for Use ("IFU"). She testified that she reviewed one other IFU, but was unaware of which version of the IFU she reviewed or whether it related to the TVT or TVT-Exact.¹⁰ Yet, Dr. Collins offers the opinion that all of Ethicon's TVT and TVT-Exact IFUs are adequate without ever having reviewed them.

Any opinion Dr. Collins might have on the IFU is based solely on her own personal perspective and belief of how surgeons like her ought to practice. Dr. Collins admits she has no knowledge at all of the regulatory or industry requirements relating to defendants' obligations to warn.¹¹ Dr. Collins was quite candid in her deposition in admitting that her opinions regarding the adequacy of defendants' warnings are based on no objective standards at all – no criteria of any kind. In fact, Dr. Collins testified that she felt regulations and standards, with regard to the risks included in an IFU, to be irrelevant.

2 Q. And do you believe that all risks should
3 be in an IFU?

6 A. I think it's irrelevant whether all
7 risks are in the IFU.

9 Q. So, you don't believe that all risks
10 should be in an IFU?

13 A. I think that's correct, yes.¹²

⁹ *Id.* at 121:2-13, 122:2-21, 249:20-250:13, 324:11-22.

¹⁰ *Id.* at 120:3-17, 330:1-331-13.

¹¹ *Id.* at 321:9-21.

¹² Collins 3/6/2017 Dep. at 121 (general objections omitted).

2 Q. So, you don't know as far as the
3 regulations are concerned what needs to be in an
4 IFU, is that correct?

7 A. That's correct. I approach an IFU as a
8 clinician and a surgeon.

10 Q. But not as somebody who would understand
11 the regulatory restrictions or regulatory
12 requirements of an IFU, is that correct?

15 A. Probably, although I think the IFU is
16 written for me as a surgeon. I think that I'm the
17 target audience and so insofar as the, you know --
18 I think it doesn't necessarily matter what, you
19 know, regulatory bodies would think should go in an
20 IFU. If it doesn't help me, I don't know that it's
21 relevant.¹³

Dr. Collins goes even further and testifies, without reference to any supporting material except her own personal practice and experience, that doctors should not and do not rely on IFUs, and therefore in her mind, no need exists to include comprehensive information accompanying defendants' products.

20 Q. Do you agree that a doctor should be
21 able to rely on the IFU?

24 A. I think you're in big trouble if a¹⁴

1 doctor is relying on the IFU to learn how to do a
2 sling.

4 Q. So, you don't believe that a doctor
5 should have to rely on an IFU?

6 A. Correct.

9 Q. Did you ever rely on the IFU?

10 A. I never did.

¹³ *Id.* at 122 (general objections omitted).

¹⁴ *Id.* at 249 (general objections omitted).

11 Q. Did you ever review the IFU prior to
12 implanting the mesh?

13 A. That's not my process, no.¹⁵

Even when questioned by Ethicon's counsel as to the basis of her opinions on the adequacy of the IFU, Dr. Collins testified that her opinions are based on her own personal practice and experience and what she personally believes should be the case for other similarly trained surgeons.

11 Q. Dr. Collins, do you have expertise as it
12 relates to what is needed to be included within an
13 IFU from a physician's perspective?

16 A. Sure.

18 Q. And what is the basis for that opinion?

19 A. I am a surgeon that implants TVT and
20 there are very few things that I need from an IFU,
21 and I think that most well-trained surgeons are the
22 same in that respect.¹⁶

Dr. Collins' opinions are completely subjective, based on her own personal belief that surgeons like herself need not rely on any IFUs. Therefore, it is her unscientific opinion that whatever Ethicon chose to include in their IFUs is "irrelevant." In fact, Dr. Collins made no attempt to ascertain, for instance, that defendants' executives have repeatedly acknowledged that IFUs must warn of all significant risks. In fact, she specifically chose to ignore internal Ethicon documents and deposition transcripts of corporate witnesses when forming her opinions and drafting her report.¹⁷ By way of example only, Dr. Charlotte Owens, Ethicon's prior worldwide medical director, testified that IFUs must clearly and unambiguously communicate all

¹⁵ *Id.* at 250 (general objections omitted).

¹⁶ *Id.* at 324 (general objections omitted).

¹⁷ Collins 3/6/2017 Dep. at 145:5-8, 146:6-147:6, 317:11-22.

contraindications, warnings, precautions and adverse events to physicians.¹⁸ Dr. David Robinson, the director after Owens left, testified that physicians rely on IFUs, hence any substantial risk must appear there.¹⁹ Sean O'Bryan of the Regulatory Affairs Division testified that both company policy and FDA regulations mandate that all warnings of substantial risks appear in the IFUs.²⁰ It is clear that Dr. Collins ignored these standards since she would have to admit the standards were violated; instead she relies on an illusory subjective standard based on her own personal practice and experience that cannot be tested. Simply put, Dr. Collins admits her opinion is based solely on her own subjective beliefs. Translated: "It is so because I say it's so" – the very essence of *ipse dixit*.²¹ Therefore, Dr. Collins' opinions on the adequacy of Ethicon's TVT and TVT-Exact warnings should be precluded.

II. Dr. Collins' General Opinions on the Design and Scientific Properties of the TVT and TVT-Exact Should Be Precluded or Limited.

Even though Dr. Collins does not have any experience in material science and has never analyzed, tested, or studied polypropylene mesh, she arbitrarily offers opinions regarding the properties of polypropylene used in Ethicon mesh products.²² Specifically, she opines that polypropylene is inert, does not undergo mechanical changes, and that the material properties of polypropylene do not have any clinical significance for patients.²³ Dr. Collins simply does not have the requisite experience to proffer this opinion, nor has she utilized *any* method—let alone a reliable method—to reach these conclusions. Dr. Collins' opinions amount to nothing more than

¹⁸ Dr. Owens Dep. Tr., 259:5-9; 260:12-261:6; 262:7-13; 309:23-310:3 (attached as Ex. E).

¹⁹ Dr. Robinson Dep. Tr., 488:11-18, 489:4-10; 492:23-493:8; 458:18-459:2, 459:12-19 (attached as Ex. F).

²⁰ O'Bryan Dep. Tr., 107:3-21; 327:22-328:7 (attached as Ex. G).

²¹ "*Ipse dixit*" is "a statement relying for truth upon the fact it has been said; and which is not independently justified or corroborated." JOHN GRAY, *LAWYER'S LATIN: A VADE-VECUM* 76 (2002).

²² See Ex. B.

²³ See Ex. B; Collins 3/6/2017 Dep. at 207:21-208:2.

baseless assumptions, and the law is clear that such “unsupported speculation” is not only insufficient, but precisely what *Daubert* aims to prevent.²⁴

A. Dr. Collins has insufficient knowledge, skill, experience, training and education to opine on the design of the TVT and TVT-Exact Mesh Devices.

Dr. Collins is a board certified Obstetrician/Gynecologist with a practice focused on female urology and pelvic floor medicine.²⁵ Dr. Collins also does not have any specialized education or training or applicable relevant experience specifically related to the design of polypropylene mesh devices.²⁶ In fact, Dr. Collins readily concedes that she is not an expert in designing mesh devices and has no knowledge of the design process:

13 Q. But you're not an expert in actually
14 designing the weave of the mesh, is that correct?

17 A. That's correct.

19 Q. Are you an expert when it comes to
20 developing the weight of the mesh?

23 A. I am not an expert in developing the
24 weight of the mesh.²⁷

2 Q. What about in determining the pore size,
3 are you an expert in determining the pore size of
4 the mesh?

7 A. No.²⁸

8 Q. Doctor, you mentioned earlier that you
9 had never designed a medical device. Have you
10 worked with any companies in designing a medical
11 device?

12 A. No.

²⁴ *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3(4th Cir., Sept. 8, 1997) (the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

²⁵ Ex. B at 2; Ex. C.

²⁶ *Id.*

²⁷ Collins 3/6/2017 Dep. at 125 (general objections omitted).

²⁸ *Id.* at 126 (general objections omitted).

13 Q. And, so, you would not be knowledgeable
14 as to the analysis that's -- that has to be done
15 before a medical device goes onto the market, is
16 that correct?

19 A. Yeah, it feels repetitive, but yeah.

21 Q. Have you ever reviewed a design history
22 file for the TVT?

23 A. I don't know what a design history file
24 is.²⁹

4 Q. Do you know what an FMEA or Failure
5 Modes and Effect Analysis is?

6 A. No.

7 Q. And you don't know what it's used for,
8 correct?

9 A. That's correct.³⁰

Despite her admitted lack of education, experience, training and knowledge about the design process of polypropylene mesh devices, Dr. Collins attempts to opine on the design, including weight and porosity, of the TVT and TVT-Exact mesh devices. These opinions undoubtedly exceed the bounds of her qualifications.

B. Dr. Collins has insufficient knowledge, skill, experience, training and education to opine on the scientific, chemical, or structural properties of the TVT and TVT-Exact Mesh Devices and does not use any reliable methodology, to form her opinions relating to the properties of the Polypropylene Mesh

Dr. Collins does not have any specialized education or training specifically related to the scientific, chemical or structural make-up of Ethicon's TVT and TVT-Exact mesh devices and/or

²⁹ *Id.* at 290 (general objections omitted).

³⁰ *Id.* at 291 (general objections omitted).

any of its components including the polypropylene mesh.³¹ Dr. Collins does not extend herself to be qualified as an expert in the subjects of biomaterials engineering, biomechanical engineering, chemistry, chemical engineering, polymer chemistry but instead concedes that she “. . . is not a chemist. . . . know[s] basic chemistry.”³² Without sufficient knowledge, skill, training, or experience, Dr. Collins attempts to opine on the properties of the TVT and TVT Exact mesh devices, such as degradation, inertness, weight, density, porosity, and cut (laser or mechanical) of the polypropylene mesh.³³ She applies no reliable methodology in forming her opinions. She has never examined pre-implant mesh or explanted mesh under a microscope.³⁴ Dr. Collins has never examined and compared the differences between mechanical and laser cut mesh even though she opines that they are equivalent.³⁵ Furthermore, Dr. Collins did not rely on any internal Ethicon documents or corporate witness testimony in forming any of her opinions. She specifically testified that she believed internal Ethicon documents to be irrelevant and unhelpful in generating her expert report.³⁶ As demonstrated below, Dr. Collins further testified that had she garnered information from Ethicon relating to the safety and properties of the mesh such as collapsibility of the pores, weight of the mesh, and inertness or degradation of the mesh, she likely would not have considered the information in forming her opinions.

4 Q. And if Ethicon had knowledge that the
5 pore sizes -- that the pores did collapse under
6 pelvic pressure, would that be information that you
7 would have considered in generating your report?

10 A. Probably not.³⁷

1 Q. Do you believe a lighter weight mesh

³¹ Ex. B at 2-3; Ex. C.

³² Collins 3/6/2017 Dep. at 124:15-125:2, 287:23-289:6.

³³ See Ex. B; Ex. C.

³⁴ Collins 3/6/2017 Dep. at 215:24-216:13

³⁵ *Id.* at 74:17-20.

³⁶ *Id.* at 138:4-140:1.

³⁷ *Id.* at 194 (general objections omitted).

2 would have a better safety profile?

5 A. I do not.

7 Q. And even if Ethicon's own scientist
8 believe that a lighter weight mesh would have a
9 better safety profile, you would not consider that
10 information in your opinions?

13 A. I would not.

15 Q. Have you done any -- have you reviewed
16 any of the testing done by Ethicon?

17 A. No.³⁸ (201)

19 Q. So, what I'm just trying to clarify is
20 that if you had seen tests with results from
21 Ethicon that showed that the polypropylene was not
22 inert, would you have considered that in generating
23 your report?³⁹
(209)

2 A. I mean I think the Thames paper is
3 irrefutable, and I have that data. So, I'm not
4 sure that there is anything that I could read from
5 an internal document from Ethicon that would change
6 my mind about that.⁴⁰ (210)

Although Dr. Collins testified that she reviewed the applicable Material Safety Data Sheet ("MSDS") for the polypropylene used to manufacture the TVT and TVT-Exact devices, she testified that she did not consider the data in the MSDS and certainly did not rely on the MSDS in formulating her opinions.⁴¹ Dr. Collins also did not consider how any additives or antioxidants added to the polypropylene may affect the mesh material, and she did not consider any tests that Ethicon may have performed on the polypropylene. When questioned whether she

³⁸ *Id.* at 201 (general objections omitted).

³⁹ Collins 3/6/2017 Dep. at 209 (general objections omitted).

⁴⁰ *Id.* at 210 (general objections omitted).

⁴¹ *Id.* at 211:8-212:5.

had tested the potential effects of the additives on the polypropylene, she testified that she did not “see that that’s necessary.”⁴²

Plaintiffs do not need to challenge Dr. Collins’ opinions based on their accuracy. The pertinent question to her analysis is not whether she is right or wrong, but whether her methods in formulating her opinions are objective and reliable.⁴³ Dr. Collins has admittedly ignored a large body of evidence and did not use any reliable methodology to come to her conclusions on the design and properties of the TVT and TVT-Exact mesh devices. Thus, expert speculation such as this should necessarily be excluded.⁴⁴

This Court has previously precluded or limited expert opinions where experts have similarly admitted to an inadequate basis, and failure to apply objective standards, in offering general opinions. For example, in precluding the warning opinions of Ethicon defense expert Denise Elser, in the *Bellew* case, the Court found:

Dr. Elser’s familiarity with IFU’s comes solely from her clinical practice... (Q: You’re just basing that on your own opinions based on your own experience and what you think is reasonable. Is that fair? A: That’s fair.”). In fact, she admits that she did not even know that there were regulations governing what information must be provided in the IFU.⁴⁵

In precluding the warning opinions of Ethicon’s other failure to warn expert in the *Bellew* case, Dr. Christina Pramudji, this Court focused as well on the expert’s admission that she did not rely on any FDA or internal Ethicon standards in offering her opinions.⁴⁶

⁴² *Id.* at 212:11-213:13.

⁴³ *See Westberry*, 178 F.3d at 261(the focus is on the principles and methodology, not the conclusions reached. Further, the court need not determine if expert testimony is irrefutable or necessarily correct.)

⁴⁴ *Oglesby v. GMC*, 190 F.3d 244, 250 (4th Cir. 1999)(“A reliable expert opinion must be based on scientific, technical, or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or other valid methods.”)

⁴⁵ *Bellew v. Ethicon, et al.*, No. 2:13-cv-22473 at 33, (S.D. W.Va. Nov. 20, 2014) [Document 265].

⁴⁶ *Id.* at 36.

Dr. Collins' deposition testimony demonstrates that she has no objective opinions, and in fact applied no standards in forming the opinions that she does have. The failure to take into account an objective standard, not even the standards Ethicon agreed were applicable, is fatal to these opinions. This Court's ruling in the *Bellevue* case is directly applicable in this situation, where the testimony goes even further in establishing the expert's lack of qualification or foundation to give her general opinions on warnings and design defect, to the extent she actually holds such an opinion. Thus, the opinions are precluded under *Daubert*.

CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that the Court exclude the above opinion testimony from Sarah Abbie Collins, regarding (a) the adequacy of the TVT and TVT-Exact warnings and (b) opinions regarding the design and scientific properties of the TVT and TVT-Exact mesh devices. Plaintiffs further request all other relief to which they are entitled.

Respectfully submitted,

/s/ Bryan F. Aylstock
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com
Attorneys for Plaintiffs

Dated: April 13, 2017

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 13, 2017, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ Bryan F. Aylstock
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com